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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/600,446

06/20/2003

Suping Jiang

WRAIR 02-42

7205

7590

10/16/2006

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EXAMINER

KANTAMNENI, SHOBHA

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/600,446	JIANG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Shobha Kantamneni	1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 12-26 and 32-71 is/are withdrawn from consideration.
- 5) ☒ Claim(s) NONE is/are allowed.
- 6) ☒ Claim(s) 1-11, 27-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This application filed on 06/20/2003, claims benefit of 60/390,334, filed on 06/20/2002.

Claims 1-71 are pending.

### ***Election/Restrictions***

Claims 12-26, 32-71 are withdrawn from consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions.

Applicant's election with traverse of invention Group I, claims 1 (in part), 2-11, 27-31 drawn to a method for the treatment of protozoan infections comprising administering a quinazolinone compound, wherein the quinazolinone compound is febrifugine/isofebrifugine, and compound of structure as in claim 27 in the reply filed on 06/20/2006 is acknowledged. Applicant's arguments have been considered, but not found persuasive because the compounds used in the methods differ by a significant structural feature, for example the compound WR089904 containing a 5-membered ring with 2 oxygen atoms is significantly different in structure from febrifugine, and thus these different compounds will have different physical, chemical, and biological properties, and activities. Although the search for these compounds, and method using the compounds maybe overlapping, the search is not coextensive. A reference which would anticipate, or make obvious, any inventions from groups I-V would not necessarily obviate or anticipate, the inventions in any other group. Further, it is

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respectfully pointed out that not restrict would place a serious examination burden on the office. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-11, 27-31 are examined herein as they read on the elected invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Takaya et al. (J. Med. Chem. 1999, 42, pages 3163-3166, PTO-892).

Takaya et al. disclose a method of treating protozoan infection by administering an effective amounts of quinazolinone compounds such as febrifugine, Df-1(3). The compounds therein are effective against *P.falciparum*, and *P.berghei*. It is also disclosed that Df-1, compound 3, was found to be equally effective against *P.berghei in vivo* as the clinically used drug chloroquine. The compounds therein are administered intraperitoneally. See abstract; page 3164, right hand column, Table 2.

Thus, Takaya et al. anticipates instant claims 1-11.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

Claims 1-2, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Takeuchi et al. (Trends in Heterocyclic Chemistry, Vol.7, 2001, pages 65-74, PTO-892).

Takeuchi et al. discloses a method of treating protozoan infections by administering effective amounts of febrifugine, or isofebrufugine. Febrifugine derivatives include quinazolinone compound as instantly claimed in claim 27. See abstract; Figure 1, page 65; page 72, Figure 4. It is also disclosed that febrifugine (+) possess antimalarial activity, and is useful in the treatment of protozoan infections which include protozoa such as *P.falciparum*, and *P.berghei*. See page 73, Table III. In vivo, and in vitro data is also disclosed.

Thus, Takeuchi et al. anticipates instant claims 1-2, 7.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

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Claims 1-2, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al. (EP 1 076 057, PTO-892).

Kobayashi et al. discloses a method of treating protozoan infections by administering effective amounts of febrifugine, or isofebrufugine. See abstract. It is also disclosed that febrifugine (+) possess antimalarial activity, and is useful in the treatment of protozoan infections which include protozoa such as *P.falciparum*. See page 8, paragraph [0049]-page 10, paragraph [0061].

Thus, Takeuchi et al. anticipate instant claims 1-2, 7.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takaya et al. (J. Med. Chem. 1999, 42, pages 3163-3166, PTO-892) as applied to claims 1-11 above, and further in view of Takeuchi et al. (Trends in Heterocyclic Chemistry, Vol.7, 2001, pages 65-74, PTO-892).

Takaya et al. is as discussed above.

Takaya et al. does not explicitly teach the employment of particular quinazolinone compound as in claim 27, in the method of treating protozoan infections.

Takeuchi et al. discloses a method of treating protozoan infections by administering effective amounts of febrifugine, or isofebrufugine. It is further taught that febrifugine derivatives are also screened for antimalarial activity, and febrifugine derivatives therein include compound as in claim 27. See abstract; Figure 1, page 65; page 72, Figure 4, 16f.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ the particular quinazolinone compound as in claim 27 for treating protozoan infections, wherein protozoa is *plasmodium falciparum* or *plasmodium berghei*.

One of ordinary skill in the art at the time of invention would have been motivated to administer quinazolinone compound as in claim 27, with reasonable expectation of treating protozoan infections because febrifugine is known to be useful in the treatment of protozoan infections, wherein protozoa is *plasmodium falciparum* or *plasmodium berghei*, and according to Takeuchi et al. the particular quinazolinone compound as in claim 27 is a derivative of febrifugine. Thus, one of ordinary skill in the art at the time of invention would reasonably expect that the derivatives of febrifugine would have similar properties and therapeutic effects as febrifugine. Note that Takeuchi et al. teaches that febrifugine derivatives were screened for antimalarial activity.

Therefore, one of ordinary skill in the art would have been reasonably expected that the instant particular quinazolinone derivaitve, would have same or substantially

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similar beneficial therapeutic effects and usefulness as febrifugine in methods for treating protozoan infections, based on the reasonable expectation that structurally similar species usually have similar properties. See, e.g, Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214, and if the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species. In fact, similar properties may normally be presumed when compounds are very close in structure. Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904, as noted in MPEP 2144.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.



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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D  
Patent Examiner  
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A handwritten signature in black ink, appearing to read 'S. Padmanabhan', is positioned above the printed name and title.

**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**